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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,970	10/29/2003	Mohan Gopalkrishna Kulkarni	11378.52US01	8985

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EXAMINER

BERNSHTEYN, MICHAEL

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/697,970	Applicant(s) 10 KULKARNI ET AL.	
	Examiner Michael Bernshteyn	Art Unit 1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 4-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to the composition for block copolymers, classified in class 526, subclasses 218.1 and 319.
 - II. Claims 4-12, drawn to process of preparation of block copolymers, classified in class 526, subclass 199.
 - III. Claims 13-17, drawn to method of preventing and/or treating, classified in class 424, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and III are related as process of making, product made and method of treatment. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be obtained by materially different processes, such as, for example, ATRP of monomers (2) and (3) in the presence of a transitional metal catalyst, etc.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and III, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4 and 13 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single ultimate disclosed specie for each of the above genera for the prosecution on the merits to which claims shall be restricted if no generic claim is finally held allowance. Where the specific species are not identified in the claims, an applicant should elect specific specie from the specification. An alternative method of election is to identify an example, which collectively exemplifies the elected species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Mr. Mark Skoog on July 28, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected invention.

Applicant is also required to elect the species, as indicated above.

6. Claims 1-3 are active in the Application.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

8. The information disclosure statement (IDS) was not submitted on 10/29/2003 and after the mailing date of the Application 10/697181 on 10/29/2003. The submission must be in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has to be considered by the examiner.

Specification

9. The disclosure is objected to because of the following informalities. The summary of the invention includes unnecessary details (please, delete the paragraphs beginning with line 1 through line 30 of the page 14).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "extraordinarily" in claim 1 is a relative term, which renders the claim indefinite. The term "extraordinarily" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

The terms "stable" and "usable" in claim 2 are relative terms, which renders the claim indefinite. The terms "stable" and "usable" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Terminology used inconsistent with accepted meaning. While applicant may be his or her lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See In re Hill, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "stable" in claim 2 is used by claim to mean "stability to enzyme from hydrolysis" (see specification, page 22, lines 19-20) while the accepted meaning is "a balanced condition not readily destroyed; as, photo-stable" ("Hackh's Chemical Dictionary", 4th Edition, 1984, page 632). The term "usable" in claim 2 is used by claim to mean "to be used for inhibition of viral infections and the recoveries of biomolecules" (see specification, page 12, lines 22-23) while the accepted meaning is "capable of being used or convenient and practicable for use" ("Merriam-Webster Online", www.onelook.com).

11. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is completely unclear from the claim 1 and from the specification what is the molecular weight range for tri-block copolymers: between 2,000 Daltons to 200,000 or between 2,000 Daltons to 2,000,000?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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12. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomis (U.S. Patent 6,403,758) in view of Mandeville et al. (U.S. Patent 5,891,862).

Loomis discloses crosslinked compositions formed from a water-insoluble copolymer. These compositions are copolymers having a **bioreasonable region**, a hydrophilic region and at least two crosslinkable functional groups per polymer chain (abstract). He discloses that said copolymer is selected from the group consisting of di-block copolymers, **tri-block copolymers**, and star copolymers (claim 6, col. 12, lines 41-44) and said tri-block copolymer has the general formula: $xABAx$ wherein A is the bioresorbable region, B is the hydrophilic region, and x is the crosslinkable functional group (claim 7, col. 12, lines 45-53).

The bioresorbable region includes without limitation, for example, poly(esters), poly(hydroxyl acids),...**polysaccharides** and mixture of them (col. 5, lines 33-38). He discloses that the composition of the present invention also includes a plurality of crosslinkable functional groups. Any crosslinkable functional group can be incorporated into the present composition (col. 5, lines 63-65). Preferably at least two olefinically unsaturated functional groups are present on the polymer chain of the present composition (col. 6, lines 17-20).

The hydrophilic region can include without limitations, for example polyethers, polyalkylene oxides, polyols, poly(vinyl pyrrolidine), poly(vinyl alcohol), poly(alkyl oxazolines), polysaccharides, carbohydrates, peptides and copolymers and mixtures thereof. Furthermore, the hydrophilic region can also be, for example, a poly(alkylene)

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oxide. Such poly(alkylene) oxides can include, for example, poly(ethylene) oxide, poly(propylene) oxide and mixtures and copolymers thereof (col.5, lines 54-62).

Loomis does not disclose using of sulfur atoms in a spacer group, which is attached to the bioresorbable region and these sulfur atoms substitute one or more carbon atoms in the main chain.

Mandeville discloses polymerizable monomers comprising a fucoside moiety which is attached by a spacer group for example, an alkylene group, or an alkylene group, wherein one or more carbon atoms are substituted by heteroatoms, such as oxygen, nitrogen or **sulfur** atoms. The polymer can be a homopolymer or a copolymer (abstract). He discloses that a spacer group can be a straight chain or branched, substituted or unsubstituted alkylene group, wherein, optionally, one or more carbon atoms are substituted by heteroatoms, such as oxygen, nitrogen or **sulfur** atoms. Examples include a $-(CH_2)_n-$ group, wherein n is an integer from about 2 to about 12, a substituted alkylene group, such as $-(CH_2)_2 O[(CH_2)_2 O]_n-$, $-(CH_2)_2 -$, wherein n is an integer, or a thiaalkylene group, such as $-(CH_2)_n S(CH_2)_m -$, where n and m are each an integer (col. 3 lines 10-18 and 41-43).

Mandeville discloses that the polymer characterized by polymerized monomer of Formula III containing polysaccharide residues (fucoside moiety) can be polymerized via a spacer group containing **s-heteroatom** (abstract), wherein this spacer group is substantially identical to the one instantly claimed (col. 3, lines 52-59 and col. 24, lines 3-12). Furthermore, by the virtue of copolymerization of two fucoside-bearing

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monomers with the same activity towards each other, as in Mandeville, the block copolymer is inherently formed (claim 12, col.24, lines 38-40).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to obtain a tri-block copolymers from two bioresorbable regions and one hydrophilic region as taught by Loomis using the S-R-S containing spacer groups as taught by Mandeville in order to increase the hydrophilic (affinity for water) of the resulting material or substance and also for creation the compositions when placed in contact with an aqueous environment form hydrogels which are useful as sealant for porous materials and particularly for implantable prostheses. Furthermore, these hydrogels can be used as delivery vehicles for therapeutic agents as suggested by Loomis (col. 1, lines 20-28 and col. 5, lines 47-48). These two references essentially show that such polymers or copolymers comprising one or more fucoside (polysaccharide) moieties can inhibit or prevent rotavirus infection in a mammal (US'862, abstract) and thus to arrive at the subject matter of claim 1 of Application No. 10/697,970.

Conclusion

Other references used but not cited in this office include U.S. Patens 6,822,064, 6,316,606, 6,271,315, 6,187,762, 6,043,328, 6,028,164, 6,018,033, 5,587,442, 5,034,516, 4,868,289, 4,455,171, and 4,230,609 are shown on the Notice of References Cited Form (PTO-892).

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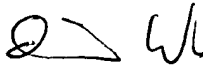
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bernshteyn whose telephone number is 571-272-2411. The examiner can normally be reached on M-F 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Bernshteyn
Patent Examiner
Art Unit 1713

MB
08/23/2005


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